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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|-------------|----------------------|----------------------|------------------|
| 10/738,427 | 12/17/2003 | Joel Morganroth | D5859-00021 | 8208 |
| 8933 | 7590 | 04/03/2007 | EXAMINER | |
| DUANE MORRIS, LLP | | | LAYNO, CARL HERNANDZ | |
| IP DEPARTMENT | | | ART UNIT | PAPER NUMBER |
| 30 SOUTH 17TH STREET | | | 3766 | |
| PHILADELPHIA, PA 19103-4196 | | | | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 04/03/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | |
|------------------------------|----------------------------------|-------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/738,427 | MORGANROTH, JOEL |
| | Examiner Carl H. Layno | Art Unit 3766 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 January 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-8, 10-18 and 20-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 1-5, 10-15, 20, 43 and 44 is/are allowed.
- 6) Claim(s) 6-8, 16-18, 21, 22, 26-30, 32, 33, 37-41, 45-48, 50-52 and 54 is/are rejected.
- 7) Claim(s) 23-25, 31, 34-36, 42, 49 and 53 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 17 December 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Acknowledgment is made of applicant's amendment, which was received by the Office on January 10, 2007.
2. Claims 9 and 19 are canceled. Claims 1-8, 10-18, and 20-54 are active and pending.

Claim Objections

3. Claims 49 and 53 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The method step of claim 49 does not appear to further limit the method step of parent claim 47 since both state the step of "receiving an identification of interval points for a plurality of intervals" associated with "at least two heartbeats".

Likewise, the details of claim 53 do not appear to further limit those already recited in parent claim 51 since both recite a "means for receiving an identification of interval points for a plurality of intervals" associated with "at least two heartbeats".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 6, the statement in lines 8-9 of the claim: "providing said ECGs to at least one evaluating physician and respective interval duration measurement data for medical evaluation" is confusing and, possibly, incomplete. To overcome this ambiguity, the Examiner recommends rewording this statement by inserting the words "on a display" between the phrases "duration measurement data" and "for medical evaluation" so that the claim is consistent with the wording of sister claim 16.

In regard to claim 16, the language of line 13 is inconsistent with the rest of the claim. It is unclear if the language in line 13 is incomplete and lacking additional language. Specifically, the statement "automatically flagging at least one ECG" is synonymous with a method step, whereas all of the other details in claim 16 are "means" for performing a function. To be consistent with the rest of the claim and to overcome this rejection, the Examiner recommends changing line 13 to read "means for automatically flagging at least one ECG".

Claims 7, 8, 17, 18, 45, and 46 are also rejected since they depend from a rejected base claim.

Claim Rejections - 35 USC § 102

6. The indicated allowability of claims 21, 32, and their depending claims is withdrawn in view of the newly discovered reference(s) to Williams (US 5,669,391) and Powell (US 5,549,654). Rejections based on the newly cited reference(s) follow.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 21, 26, 27, 32, 37, 38, 47, 48, 50-52, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams (US 5,669,391).

In regard to claims 21 and 32, the Williams patent (US 5,669,391) discloses an ECG monitoring system whose features and method of operation read upon applicant's claims. Specifically, the Williams system comprises an implantable pulse generator **12** and an external instrument **13** (Fig.1). Pulse Generator **12** receives ECG data from sensors **17** and digitizes this data and formats it in data frames for uplinking to the external instrument via wireless telemetry (col.5, lines 15-50). Once received by the external instrument **13**, the data is processed and displayed to a physician as shown in Fig.6. The display of Fig.6 shows a plurality of a patient's ECG signals over a plurality of heartbeats as well as measured interval duration information and annotations. Detected R-wave maximums perform the function of applicant's claimed "interval points" for determining the beginning and ending of intervals. The annotation data regarding signal morphology classification of an interval (i.e. tachycardia, fibrillation, non-tachycardia, etc.) and interval duration are stored in memory **25** (Fig.2 and also col.7, lines 9-64).

In regard to claims 26, 37, 47, and 51, a plurality of points (R-wave maximums) that define a plurality of intervals are shown in Figs.5 and 6.

In regard to claims 27, 38, 48, and 52, the intervals shown in Figs.5 and 6 appear to be R-R intervals.

In regard to claims 50 and 54, applicant's attention is directed to Fig.6, which shows annotated ECG waveform data over a plurality of heartbeat cycles being displayed on a screen.

9. Claims 21, 22, 28-30, 32, 33, 39-41, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Powell (US 5,549,654).

In regard to claims 21 and 32, the Powell (US 5,549,654) patent describes a body implantable medical device (Fig.1) receiving ECG data from implanted leads **14,15**, then digitizing and processing this data through digital controller **31** before uplinking this data via telemetry circuit **33** and antenna **23** to an external programmer (Fig.2). External programmer (Fig.2) comprises a display **54** that shows a plurality of sensed ECG signals **102** (Fig.3) and annotated ECG tracing information **106** on the same screen. Intervals are measured between left and right cursor bars (shown but not numbered in Fig.3) which may be scrolled via position buttons on the screen, or alternatively, shown as elements **152,154** in Fig.7. As shown in Fig.3, a 25mm (1 inch) distance on the screen represents a time duration of one second. Hence, for the example of Fig.3, the distance between the cursors bars is currently 1000ms, or 1 second. The location of the cursor bars is considered to be the "interval points". Figs.4 through 7 describe annotated ECG "tracing images"/Marker Channels showing the location of saved paced events (P) and sensed events (S). The programmer is capable of capturing and storing at least 10 seconds worth of ECG data (col.12, lines 64 thru col.13, line 7).

In regard to claims 22 and 33, applicant's attention is directed to Fig.7, which shows vertical "calipers" **152,154** which can be moved for selecting points on the ECG waveform.

In regard to claims 29 and 40, applicant's attention is directed to Fig.6 of Powell, which shows an annotated ECG tracing and explanation box **156**. This box supplies the evaluating physician with useful explanations regarding the ECG interval under study (col.15, line 59 thru col.16, line 9).

In regard to claims 28 and 39, the Powell implantable device includes lead **15** for sensing atrial cardiac signals and lead **14** for sensing ventricular cardiac signals.

In regard to claims 30 and 41, a stylus **76** may be used to retrieve interval information by "pointing and clicking" on screen **54** to activate explanatory text box **156** (col.15, liens 46-50). This box may contain interval data such as AV interval duration (col.15, lines 63-67).

In regard to claim 54, the external programmer (Fig.2) is capable of performing the functions of applicant's claimed "means for retrieving", "means for developing" and "means for displaying" since it retrieves ECG data from the implantable device (Fig.1), processes the ECG data by adding annotations, and displays the annotated data on a screen (Figs. 3 and 7).

Double Patenting

10. In view of the applicant's submission and approval of a Terminal Disclaimer, the Examiner is withdrawing the double patenting rejections based upon U.S Patent No. 6,708,057, which were made against applicant's claims 1, 4, 5, and 6 in the last Office action.

Allowable Subject Matter

Art Unit: 3766

11. Claims 6 and 16 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

12. Claims 7, 8, 17, 18, 45, and 46 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

13. Claims 23-25, 31, 34-36, and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Claims 1-5, 10-15, 20, 43, and 44 are allowed.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Carl H. Layno

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CHL
3/28/2007